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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|---------------|----------------------|-------------------------|------------------|
| 10/082,415 | 02/26/2002 | Michael J. Pugia | MSE #2645 | 8582 |
| 75 | 90 09/26/2005 | | EXAMINER | |
| Elizabeth A. Levy | | | SIEFKE, SAMUEL P | |
| Bayer HealthCare LL Two Edgewater Drive | | | ART UNIT | PAPER NUMBER |
| Norwood, MA 02062-4637 | | | 1743 | |
| | | | DATE MAILED: 09/26/2005 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|--|--|--|-------------|
| | Application No. | Applicant(s) | : |
| | 10/082,415 | PUGIA ET AL. | |
| Office Action Summary | Examiner | Art Unit | |
| | Samuel P. Siefke | 1743 | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with | the correspondence address | |
| • • | V 10 05T TO 5VDIDE - 1401 | TT (() | _ |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICA 136(a). In no event, however, may a reply will apply and will expire SIX (6) MONTHS e, cause the application to become ABAN | TION. be timely filed from the mailing date of this communication DONED (35 U.S.C. § 133). | |
| Status | | | |
| 1)⊠ Responsive to communication(s) filed on 7/11. | /05 | | |
| | s action is non-final. | | |
| 3) Since this application is in condition for allowa | | prosecution as to the merits | is |
| closed in accordance with the practice under t | · | • • | |
| Disposition of Claims | | | |
| 4)⊠ Claim(s) <u>1,5-13,16-18 and 38-50</u> is/are pendin | ng in the application. | | |
| 4a) Of the above claim(s) is/are withdra | | | |
| 5) Claim(s) is/are allowed. | | • | |
| 6)⊠ Claim(s) <u>1,5-13,16-18 and 38-50</u> is/are rejecte | ed. | | |
| 7) Claim(s) is/are objected to. | | | |
| 8) Claim(s) are subject to restriction and/o | or election requirement. | | |
| Application Papers | | | |
| 9) The specification is objected to by the Examine | er. | | |
| 10) The drawing(s) filed on is/are: a) acc | | the Examiner | |
| Applicant may not request that any objection to the | , , , | | |
| Replacement drawing sheet(s) including the correct | tion is required if the drawing(s) | s objected to. See 37 CFR 1.121 | (d). |
| 11) ☐ The oath or declaration is objected to by the Ex | kaminer. Note the attached O | ffice Action or form PTO-152. | |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 11 | 9(a)-(d) or (f). | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | |
| 1. Certified copies of the priority document | | | |
| 2. Certified copies of the priority document | | | |
| Copies of the certified copies of the prio application from the International Burea | | eived in this National Stage | |
| * See the attached detailed Office action for a list | · · · · · · · · · · · · · · · · · · · | aived | |
| coo the attached detailed emice detail for a list | or the certifica copies not rec | eived. | |
| Attachment(s) | | | |
| 1) X Notice of References Cited (PTO-892) | 4) Interview Sum | many (PTO-413) | |
| 2) D Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/M | ail Date | |
| Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Inform 6) Other: | nal Patent Application (PTO-152) | |
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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by McNeely et al. (USPN 6,296,020).

McNeely discloses a fluid circuit that is based upon passive fluid dynamics.

McNeely device comprises a plurality of sample well (fig. 3a-3d; col. 10, lines 13-15) a hydrophilic capillary passageway that is in fluid communication with sample well for receiving a sample by capillary action (col. 5, lines 39-41), the passageway including a segment defining the volume of a uniform liquid sample, the segment disposed between two vents to the atmosphere (col. 4, lines 8-10; col. 4, lines 50-55; fig. E-G; col. 9, lines 19-60; col. 11, lines 1-16), a hydrophilic capillary stop disposed within the hydrophilic capillary passageway for preventing sample transport until the resistance of the stop is overcome by a force other than centrifugal force (col. 5, lines 50-59; col. 6, lines 11-47; col. 8, lines 64-68; col. 9, lines 3-14).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-13,16-18,39-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeely et al. (USPN 6,296,020) in view of Kellogg et al. (USPN 6,063,589).

McNeely discloses a fluid circuit that is based upon passive fluid dynamics as discussed above.

McNeely does not specifically mention reagents as a mixing fluid nor the use of electrodes to measure a property of the fluid

Kellogg teaches a device for performing microanalytic analyses that comprises a platform that rotates, thereby utilizing centripetal forces that motivates fluid movement through microchannels embedded in the microplatform. Reagent wells contain a reagent adapted to react with a component contained in the sample and produce a

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response indicating the amount of component in the liquid sample (col. 14, lines 5-34) along with reducing the interference of the component with a second component to be detected (col. 17, lines 5-20). The first reagent well contains a reagent to pretreat the liquid sample (col. 17, lines 5-20). Electrodes are disposed in the reagent wells for measuring properties of the liquid sample (col. 53, line 66- col. 54 line 29). It would have been obvious to one skilled in the art to modify McNeely to employ an electrode to measure a property of a fluid because it is well known in the art that microfluidic devices are used for mixing samples with reagents and detecting a reaction product.

Response to Arguments

Applicant's arguments with respect to claims 1, 5-13,16-18,38-50 have been considered but are most in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke

September 16, 2005